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Examiner: P. Duffy

IN THE CLAIMS:

(For the Examiner's convenience, all of the pending claims are reproduced below.

Claims that have not been amended are indicated as "Unchanged".)

ME1 37. A method for treating an autoimmune disease in a human, the method comprising administering by nose or mouth to said human an effective amount for treating said disease of a composition comprising a bystander antigen, wherein said bystander antigen is not an autoantigen in said human and wherein said bystander antigen is not an insulin antigen.

38. The method of claim 37 wherein said bystander antigen is specific to an organ or tissue afflicted by immune attack during said disease.

39. A method for treating an autoimmune disease in a human, the method comprising administering by nose or mouth to said human an effective amount for treating said disease of a composition comprising a bystander antigen, wherein said bystander antigen is not an autoantigen, and wherein said bystander antigen is not an insulin antigen.

ME1 42. The method of claim 37 wherein said bystander is administered to said human in aerosol form.

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43. The method of claim 37 wherein said bystander antigen is administered in a dry powder form.

44. The method of claim 37 wherein said bystander antigen is administered as a saline solution.

45. The method of claim 38 wherein said administration is effective to treat said disease without causing an accompanying decrease in the blood sugar level of said human.

46. The method of claim 38 wherein said disease is Type I diabetes and said bystander antigen is glucagon.

47. A method for treating type I diabetes in a human, the method comprising administering by inhalation to said human an effective amount for treating said Type I diabetes of glutamic acid decarboxylase.

48. (Twice Amended) A pharmaceutical dosage form for treating an autoimmune disease in a human, the form consisting essentially of:

an effective amount for treating said disease of a bystander antigen; and
a pharmaceutically acceptable carrier or diluent;

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wherein said bystander antigen is not an autoantigen in said human, and wherein said dosage form is [adapted for nasal or mouth administration] contained in an inhaler or nebulizer.

49. The pharmaceutical dosage form of claim 48 wherein said bystander antigen is specific to an organ or tissue afflicted by immune attack during said disease.

52. The pharmaceutical dosage form of claim 49 wherein said dosage form is an aerosol form.

53. The pharmaceutical dosage form of claim 49 wherein said dosage form is a saline solution.

54. The pharmaceutical dosage form of claim 49 wherein said dosage form is a dry powder.

55. The pharmaceutical dosage form of claim 49 wherein said dosage form is effective to treat said autoimmune disease without causing a lowering of the blood sugar level of said human.

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56. The pharmaceutical dosage form of claim 48 wherein said disease is selected from the group consisting of Type I diabetes and animal models therefor and said bystander antigen is glucagon.

57. (Amended) A pharmaceutical dosage form for nasal [or mouth] administration for treating Type I diabetes in a human comprising an effective amount for treating said type I diabetes of glutamic acid decarboxylase and a pharmaceutically acceptable carrier or diluent in an inhaler or nebulizer.

59. The method of claim 37 wherein said bystander antigen is purified.

60. The method of claim 37 wherein said bystander antigen is substantially pure.

61. The method of claim 37 wherein said composition is substantially free of autoantigens.

62. The pharmaceutical dosage form of claim 48 wherein said bystander antigen is purified.

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63. The pharmaceutical dosage form of claim 48 wherein said bystander antigen is substantially pure.

64. The pharmaceutical dosage form of claim 48 wherein said composition is substantially free of autoantigens.

65. A method for treating an autoimmune disease in a human, the method comprising administering by nose or mouth to said human an effective amount for treating said disease of a composition comprising a bystander antigen, wherein said bystander antigen is not an antigen to which T-cells which mediate the disease are sensitized, and wherein said bystander antigen is not an insulin antigen.

REMARKS

Reconsideration of this application is respectfully requested.

Following entry of this Amendment, claims 37-39, 42-49, 52-57 and 59-65 will be pending. Claims 48 and 57 have been amended. Support for the amendment to claims 48 and 57 is found throughout page 25 of the specification.